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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,667	08/18/2000	John S. Fox	65446-0053	6732

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,667

Applicant(s)

FOX, JOHN S.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 103-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-17, 110-116 is/are rejected.
- 7) ☒ Claim(s) 10 and 103-109 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 9/24/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 18-102 and 117 are cancelled.
2. Currently, claims 1-17 and 103-116 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-17 and 103-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 18, it is not clear about the "location" with respect to the complex relationship. As recited in the claim, a magnetic field is applied to the sample containing the target molecules where a complex of the target-probe has formed. It is not clear what does the "location" of the sample means in this assay.

With respect to claim 1, line 18, it is not clear what is this "orientation" refers to. Does it mean orient to the magnetic pole or to the "spatial orientation"?

With respect to claim 15, it is not clear what is this "non-magnetic colloid".

With respect to claim 15, it is not clear about the non-magnetic colloid "so as to block the magnetic signal from the molecule complex." Applicant indicates that the non-magnetic colloid solution is used as a blocking agents to "reduce non-specific binding of probes

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and background noise.” (See page 20, last paragraph to first paragraph, page 21) It appears that the non-colloid agents are not to “block the magnetic signal from the molecule complex’ but to reduce the non-specific binding of the probes and background.

With respect to claim 113, it is not clear whether the wording of “ferromagnetic” should be “ferromagnetic” since the instant claim is a duplicate of claim 112.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5, 8, 9, 15-17 and 112-116 rejected under 35 U.S.C. 102(b) as being anticipated by Rohr, Thomas (US 5445970) are maintained.

Rohr teaches an assay to determine the presence or amount of analyte in a test sample. Rohr teaches contacting the test sample with an immobilized probe (i.e. specific affinity to the analyte) with a magnetically-labeled reagent to form analyte-probe complex, and applying a magnetic field to measure the presence or amount of the analyte in the test in the sample in response to the magnetic force. (See claim 1-6; Figure 6-14; Table 2-3)

With respect to claim 5, the probe is immobilized on a microparticles (Col. 22, line 1-10).

With respect to claims 8-9, Rohr teaches measuring the magnetic force, e.g. as a signal, to reflect the presence of the probe-target complex (Figure 1-6).

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With respect to claim 15, Rohr teaches using a non-magnetic colloid agent, e.g. biotin-BSA, to reduce the non-specific binding (See Example 11).

With respect to claims 16-17 and 112-116, Rohr teaches that magnetic materials could be superparamagnetic particles, or inherently including materials having magnetic characteristics, such as paramagnetic or ferromagnetic. (See example 1) The magnetic particles are visually identifiable, i.e. neodymium-iron-boron. (See example 1)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3, 4, 6, 7, 11-14, 110-111 rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr as unpatentable in view of Baselt et al. (US 5981297).

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With respect to claims 3-4 and 6-7, Rohr's reference has been discussed but is silent in teaching disposed probes in an addressable array for analysis. Baselt et al. teach a method of assaying target molecules by magnetic labeled beads by use of addressable array system, i.e. known locations, for convenience and economy. (See abstract, Figures 1; col. 1, line 16-18) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Rohr with the array system as taught by Baselt et al. since it relates to an analogous field (using magnetic particles measuring sample) and in a convenient and economical fashion.

With respect to claim 11-14 and 110-111, although Rohr does not specifically teach using a plurality of magnetic fields having different directions, it would have been obvious to one ordinary skill in the art at the time the invention was made to have incorporated with plurality of magnetic field array arrangement as taught by Pirrung et al. with various intensity of magnetic fields and directions for multiple detection purposes.

Response to Applicant's Argument

6. The enablement rejections of claims 1-17 and 103-116 under 35 USC §112, first paragraph, are withdrawn.

7. Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr in view of Moeremans et al. (EP 0165633) is moot in view of new ground of rejection set forth in this Office Action.

8. Claims 3, 4, 6, 7, 11-14, 110-111 rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr as unpatentable in view of Pirrung et al. (US 5143854) are moot in view of new ground of rejection set forth in this Office Action.

Rohr Thomas (US 5445970) reference

9. Applicant argues that the teachings of Rohr do not anticipate the recited invention. Applicant distinguishes that Rohr does not teach using a magnetic “signal” and a “label” as revealed in the instant invention. Applicant’s arguments have been considered but are not persuasive.

With respect to the term “signal”, applicant argues that Rohr uses “*magnetic forces*” as the “magnetic response”, whereas the instant invention is a magnetic “*signal*” in contrast with the teachings of Rohr. First, there is no definition in the current specification as to define the “signal” meaning in the claim language. In the definition of Webster’s II dictionary (1994), the definition is 1. an indicator, as a mechanical device, functioning as a means of communications; 2. a message communicated by such means; 3. an impulse or fluctuating electricity quantity, as voltage, current, or electrical field strength, whose variations represent coded information (See Attachment reference). Therefore, the magnetic force measured by Rohr is a “signal” whether manually or electrically performed as long as it functions as an indicator to communicate the results to one artisan in the art.

With respect to the issue of “label” used in Rohr, applicant argues that Rohr uses a common magnetic iron compound like Fe₂O₃ (ferric oxide). Applicant does not consider this is a label. Examiner would like to point out that in light of the specification, applicant states numerous times on the “magnetically labeled biomolecules” without specifying what other material(s) besides the probe being “labeled” (See page 6, first paragraph, last paragraph; page 8, last paragraph; page 9, first paragraph; page 13, last paragraph; page 20, second paragraph). At most, applicant asserts that “[a] magnetic label or magnetic marker is any transiently or permanently magnetized entity.” (See page 8, last paragraph) Applicant also uses the term “label” referring to the “magnetic” which means “magnetizing” by the magnetic material as illustrated in Example 3 and Example 4, where applicant uses a magnetic labeled nucleic acid probes, i.e. Example 3, and a

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ferrofluid-labeled streptavidin, i.e. Example 4, to determine the analyte. Taken together, the “magnetic labeled” term used in the instant application is encompassed by Rohr because Rohr defines that “magnetically-labeled reagent” referring to a substance involving a magnetically-attractable label attached to a binding member” (Col. 6, line 35-37).

Allowable Subject Matter

10. Claims 10, 103-109 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or fairly suggests that measuring the magnetic features, such as swing time, spatial orientation, hysteresis loop, remnant magnetization or the signal generated by a magnetoresistive ratio sensor to detect the presence, location or quantity of the target molecules. The closest prior art is the teaching of Rohr (US 5445970). However, Rohr does not disclose or suggest the above mentioned features as a measuring tool for detection of biomolecules in a sample.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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January 13, 2005


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1/18/05